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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,982	02/27/2002	Arjan Scheepens	37522-10006	8750
23910	7590	07/05/2005	EXAMINER	
FLIESLER MEYER, LLP FOUR EMBARCADERO CENTER SUITE 400 SAN FRANCISCO, CA 94111			JIANG, DONG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/786,982

Applicant(s)

SCHEEPENS ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 30-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 30-58 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's preliminary amendment filed on 27 February 2002 is acknowledged and entered. Following the amendment, claims 1-29 are canceled, and the new claims 30-58 are added.

Currently, claims 30-58 are under pending.

#### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 30-33, 34 in part, 35, and 49-58, drawn to a method for inducing a neuroprotective effect in a brain with a growth hormone or with a growth hormone and a secondary neuroprotective agent, and a pharmaceutical composition comprising a suitable excipient, a growth hormone, and a secondary neuroprotective agent.

Group II, claim(s) 34 in part, 36 in part, and 37-39, drawn to a method for inducing a neuroprotective effect in a brain with an agent which stimulates production of growth hormone or the ligand.

Group III, claim(s) 34 in part, 36 in part, and 37-39, drawn to a method for inducing a neuroprotective effect in a brain with an agent which lessens or prevents inhibition of growth hormone or the ligand activity.

Group IV, claim(s) 40-41 in part, 42, 43, and 46-48, drawn to a method for inducing a neuroprotective effect in a brain with an agent which increases the activity of neural growth hormone receptors, wherein the agent binds growth hormone receptors.

Group V, claim(s) 40-41 in part, and 44-48, drawn to a method for inducing a neuroprotective effect in a brain with an agent which increases the activity of neural growth hormone receptors, wherein the agent effects an increase in the active concentration of an agent which binds neural growth hormone receptors.

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The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I invention (the main invention) is directed to a method for inducing a neuroprotective effect in a brain with a growth hormone or with a growth hormone and a secondary neuroprotective agent, and a product of use, i.e., a pharmaceutical composition comprising a suitable excipient, a growth hormone, and a secondary neuroprotective agent. The additional methods of Groups II-V inventions do not relate to the same inventive concept of that of Group I invention under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same technical feature as they require the use of compounds with distinct chemical, structural and functional properties from that of the main invention. As such, Groups II-V do not share the same technical feature with Group I invention within the meaning of PCT Rule 13.2, and thus, do not relate to a single invention concept within the meaning of PCT Rule 13.1.

### ***Species election***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Four groups of species elections are required, they are as follows:

1. A single agent binding growth hormone receptors selected from:  
(a) growth hormone, or an analog thereof, (b) prolactin, or an analog thereof, or (c) placental lactogen, or an analog thereof.
2. A single agent effecting an increase in the active concentration of an agent which binds neural growth hormone receptors selected from:  
(a) GRP, (b) GHRH, or (c) SRIF.
3. A single secondary neuroprotective agent selected from:  
(a) IGF-1, (b) GPE, (c) activin, (d) NGF, (e) TGF- $\beta$ , (f) growth hormone binding proteins, (g) IGF-binding proteins, or (h) bFGF.
4. A single neuronal insult selected from:

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(a) Huntington's disease, (b) Alzheimer's disease, (c) corticobasal degeneration, (d) Steele-Richardson-Olszewski syndrome, (e) Devic's disease, (f) Pick's disease, or (g) diabetic neuropathy.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 42 and 43 - species 1,

Claims 44 and 45 - species 2,

Claims 50, 52-55 and 57 - species 3,

Claims 52-55 - species 4,

The following claim(s) are generic: claims 40 and 41 for species 1 and 2; claim 49 for species 3; and claims 49 and 51 for species 4.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Each species within a species election set forth in species 1-3 above has distinct chemical, structural and functional properties, and therefore, these species do not share a special technical feature within the meaning of PCT Rule 13.2, and thus do not relate to a single invention concept within the meaning of PCT Rule 13.1. With respect to species 4, they are diseases or conditions with distinct causes and clinical manifestations, thus, share no special technical feature within the meaning of PCT Rule 13.2, and cannot be linked by a single general inventive concept under PCT Rule 13.1.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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**Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on 9:30 am - 7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
6/26/05

  
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